

## REMARKS

In light of the arguments presented herein, Applicant submits that claims 1-21, 23 and 24 pending in the above-identified patent application are in allowable form. Reconsideration and allowance of all pending claims is therefore respectfully requested.

It is to be understood that Applicant does not acquiesce to the Examiner's characterizations of the art of record or to Applicant's subject matter, as recited in the pending claims. Further, Applicant is not acquiescing to the Examiner's statements as to the applicability of the prior art of record to the pending claims by filing this response.

### The § 103 Rejections

At pages 2-7 of the Office Action, the Examiner rejected claims 1-2, 5-13, 18, and 23-24 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 5,873,882 to Straub et al. (hereinafter "Straub") in view of U.S. Pat. No. 4,705,511 to Kocak (hereinafter "Kocak"). Specifically, the Examiner alleges that Straub discloses all the elements of claim 1 except a distal part comprising a metallic helical spring having a thin-walled elastic plastic sheath, which is allegedly supplied by Kocak. Applicant respectfully disagrees with the Examiner for the following reasons.

Claim 1 requires a "transport screw [that] cooperates with the lateral opening of the working head for shearing and comminuting materials or aspirated and/or detached thrombi and emboli penetrating between peripheral borders of the transport screw." Similarly, claim 2 recites that a "transport screw, in the region of the working head, cooperates with the cutting tool and the lateral opening of the working head, in an operating state, to shear, continuously comminute the material or aspirated and/or detached thrombi and emboli penetrating between peripheral borders of the transport screw."

In Straub, stator 14 and rotor 16, which is disposed on the outside of stator 14 (see column 3, line 66 of Straub), have openings. Stator 14 is fastened to tubular flexible sheath 22, and rotor 16 is connected to the flexible drive shaft 32. What is important is that stator 14 remains stationary while rotor 16, along with flexible drive shaft 32, rotates (see Fig. 7 of Straub). It is the relative motion between stator 14 and flexible drive shaft 32 that produces the vacuum that draws in deposits from the walls of blood vessels. The cutting edge 16d of rotor 16 and the cutting edge 14d of stator 14 form "shearing slots" that shear stenoses and blood clots into small particles (see Fig. 3 and column 4, lines 15-50 of Straub). Flexible drive shaft 32

operates only to move particles displaced by the respective cutting edges 14d, 16d of stator 14 and rotor 16 (see column 4 lines 5-10). Note that there is no cutting action in the Straub device between the drive shaft 32 and the rotor 16 or stator 14. Thus, Straub does not disclose a working head that cooperates with a transport screw to shear thrombi and emboli, as required by claims 1 and 2.

In contrast, for example, claims 1 and 2 may cover the shearing of deposits by the interaction of a stationary working head 11 of a catheter and the rotation of a transport screw 13 (see paragraph [0021]-[0022] and FIGS. 2-3 of the instant application). The shearing of the emboli, thrombi and other materials may occur between transport screw 13 and working head 11 – as a result of the contact internally between flights of transport screw 13 and working head 11 (see paragraphs [0013] and [0020] of the instant application), not between a moving rotor and a stator.

Thus, the emboli and thrombi particles may be swept into flexible tube 12 immediately (see paragraphs [0017]-[0021] of Applicant's specification), and fewer particles are lost to the bloodstream and the bloodstream itself is subject to fewer or no vortices, an undesirable effect to be avoided (see paragraphs [0010] and [0017] of Applicant's specification). Other advantages of having no external rotor include fewer vibrations, the need for less torque/drive power, cost reductions, and no jamming between a rotor and a stator (see paragraphs [0010], [0019] and [0020] of Applicant's specification). Additionally, the catheter may have a smaller diameter, and operate in a manner far less traumatic to blood vessels. For example, the catheterization of smaller blood vessels, such as coronary vessels, is now possible (see paragraph [0020] of Applicant's specification).

With the foregoing in view, Straub does not disclose a working head that cooperates with a transport screw to shear emboli and thrombi, and therefore does not disclose each and every element of independent claims 1 or 2. The above deficiencies of Straub are not cured by Kocak, which merely discloses an introducer sheath having a flexible tube (see column 2 lines 35-50 of Kocak). Kocak does not disclose a working head or a transport screw and therefore discloses no structure capable of achieving the cutting of the emboli or thrombi. Accordingly, no combination of Straub and Kocak (and Applicant does not concede that any such combination is proper) results in a structure required by claims 1 and 2, and therefore no § 103 rejection can be maintained.

As each of claims 5-13, 18, and 23-24 depend from claim 1, include the features thereof as well as additional patentable subject matter, the subject dependent claims are therefore patentable. Accordingly, the Examiner is respectfully requested to withdraw the § 103 rejection of claims 1-2, 5-13, 18 and 23-24.

At pages 7-10 of the Office Action, the Examiner rejected claims 3-4, 14 and 25 under 35 U.S.C. § 103(a) as being obvious over Straub in view of Kocak and in further view of U.S. Pat. No. 5,312,425 to Evans et al. (hereinafter “Evans”). Claim 3 requires a “transport screw, in a region of the working head, [that] cooperates with the cutting tool and the opening of the working head and, in an operating state, to shear, continuously comminute the materials or aspirated and/or detached thrombi and emboli penetrating between peripheral borders of the transport screw and borders of the at least one lateral openings.” As discussed above with respect to claims 1 and 2, Straub does not disclose this feature, a deficiency which is not cured by either Kocak or Evans. As discussed above, Kocak discloses no such structure capable of achieving the cutting of the emboli or thrombi.

Evans also does not cure the deficiencies of Straub and Kocak. Evans discloses catheter 50 having helical cutting blade 58 that is sharpened on one or two edges 62, 64 (see FIG. 2 and column 5, lines 42-48 of Evans). Helical cutting blade 58 performs the cutting of material (see column 5, lines 50-52 of Evans). Similar to the arguments presented above, this is unlike that covered by claim 3, which requires a “working head, [that] cooperates with the cutting tool and the opening of the working head and, in an operating state, to shear, continuously comminute the materials or aspirated and/or detached thrombi and emboli penetrating between peripheral borders of the transport screw and borders of the at least one lateral openings.” Therefore, no combination of Straub, Kocak and Evans (and Applicant does not concede that any such combination is proper) results in the subject matter of claim 3, and no § 103 rejection can be maintained.

As claim 4 depends from claim 3, includes all the features thereof as well as additional patentable subject matter, claim 4 is therefore patentable. As claim 14 depends from claim 1, includes all the features thereof as well as additional patentable subject matter, claim 14 is therefore patentable. Accordingly, the Examiner is respectfully requested to withdraw the § 103 rejection of claims 3, 4 and 14. Claim 25 was canceled, its features incorporated into claim 1 in a previous response and is no longer pending.

At pages 10-11, the Examiner rejected claims 15-17 under 35 U.S.C. § 103(a) as being obvious over Straub in view of Kocak and in further view of U.S. Appl. No. 2003/0114875 to Sjostrom (hereinafter “Sjostrom”). At pages 12-13 of the Office Action, the Examiner rejected claims 19-21 under 35 U.S.C. § 103(a) as being obvious over Straub reference in view of Kocak and in further view of U.S. Pat. No. 6,217,565 to Cohen (hereinafter “Cohen”). Neither Sjostrom nor Cohen supplies the features missing from Straub, the primary reference, for example, a “transport screw [that] cooperates with the lateral opening of the working head for shearing and comminuting materials or aspirated and/or detached thrombi and emboli penetrating between peripheral borders of the transport screw,” as required by claim 1. Therefore, Sjostrom and Cohen do not cure the deficiencies of Straub. As each of claims 15-17 and 19-21 is dependent on claim 1, includes all the features thereof, as well as additional patentable subject matter, claims 15-17 and 19-21 are also allowable. Accordingly, the Examiner is respectfully requested to withdraw the § 103 rejection of the subject claims.

## Conclusion

Applicant submits that all claims presently pending in the application are in condition for allowance. If the Examiner believes that there are unresolved issues requiring adverse final action in any of the claims now pending in the application, it is requested that the Examiner telephone Matthew Dernier, Esq., at (732) 634-7634 so that appropriate arrangements can be made for the resolution of such issues as expeditiously as possible.

Early and favorable action is earnestly solicited. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

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Respectfully submitted,

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